

Prefilled syringes —

Part 2: Specification for plungers and discs for dental local anaesthetic cartridges

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/11, Transfusion equipment for medical use, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain
- Association of Clinical Pathologists
- Association of the British Pharmaceutical Industry
- Biochemical Society
- British Glass Manufacturers' Confederation
- British Medical Association
- British Plastics Federation
- British Surgical Trades Association
- Department of Health
- Guild of Hospital Pharmacists
- Institute of Materials
- Medical Sterile Products Association
- Ministry of Defence
- Royal Pharmaceutical Society of Great Britain
- Scottish National Blood Transfusion Service

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 June 1995

© BSI 10-1999

The following BSI references relate to the work on this standard:
Committee reference HCC/11
Draft for comment 93/505054 DC

ISBN 0 580 24414 8

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
1 Scope	1
2 Normative references	1
3 Classification of types	1
4 Dimensions and designation	1
5 Material	2
6 Requirements	2
7 Marking	3
Annex A (normative) Test for fragmentation	4
Annex B (normative) Leakage test	6
Annex C (normative) Test for sliding properties	7
Figure 1 — Dimensions and configuration of plungers showing positions of cavities	1
Figure 2 — Dimensions and configuration of typical discs	2
Figure A.1 — Needle point	4
Figure A.2 — Test sequence for fragmentation test	6
Table 1 — Dimensions of plungers	1
Table 2 — Chemical limits for plungers and discs	3
Table A.1 — Dimensions of bevel	4
List of references	Inside back cover

National foreword

This Part of BS 7652 has been prepared by Technical Committee HCC/11 and is identical with ISO 11040-2:1994 *Prefilled syringes — Part 2: Plungers and discs for dental local anaesthetic cartridges*, prepared jointly by Technical Committee TC 76, Transfusion, infusion and injection equipment for medical use, and TC 106, Dentistry, of the International Organization for Standardization (ISO) with the active participation of the UK.

Cross-references

Publication referred to	Corresponding British Standard
ISO 48:1994	BS 903 <i>Physical testing of rubber</i>
	Part A26:1995 <i>Method for determination of hardness (hardness between 10 IRHD and 100 IRHD)</i> (Identical)
ISO 3302:1990	BS 3734:1978 <i>Specification for dimensional tolerances of solid moulded and extruded rubber products</i> (Identical)
	BS 5081 <i>Sterile hypodermic syringes and needles</i>
ISO 7864:1993	Part 2:1993 <i>Specification for sterile hypodermic needles for single use</i> (Identical)
	Part 1:1994 <i>Specification for sterile, single-use hypodermic syringes for manual use</i> (Identical)
ISO 7886-1:1993	BS 7432:1991 <i>Specification for dental cartridge syringes</i> (Identical)
	BS 7652 <i>Prefilled syringes</i>
ISO 9997:1990	Part 1:1993 <i>Specification for glass cylinders for dental local anaesthetic cartridges</i> (Identical)

The Technical Committee has reviewed the provisions of ISO 8871:1990 and ISO 11040-3:1993, to which normative reference is made in the text, and has decided that they are acceptable for use in conjunction with this British Standard. ISO 8362-5 is in course of preparation. If ISO 8362-5 is adopted as a European standard, it will be implemented in the UK as BS EN ISO 8362-5.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This part of ISO 11040 specifies the design, dimensions, materials, performance, requirements, marking and test methods for plungers and discs for dental local anaesthetic cartridges intended for single use only.

It applies to primary packs used in direct contact with the drug.

NOTE 1 The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary pack.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 11040 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1994, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*.

ISO 3302:1990, *Rubber — Dimensional tolerances for use with products*.

ISO 7864:1993, *Sterile hypodermic needles for single use*.

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*.

ISO 8362-5:—, *Injection containers for injectables and accessories — Part 5: Freeze drying closures for injection vials¹⁾*.

ISO 8871:1990, *Elastomeric parts for aqueous parenteral preparations*.

ISO 9997:1990, *Dental cartridge syringes*.

ISO 11040-1:1992, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*.

ISO 11040-3:1993, *Prefilled syringes — Part 3: Aluminium caps for dental local anaesthetic cartridges*.

3 Classification of types

3.1 Plungers

Plungers shall be classified as follows:

Type A: Plungers without cavities;

Type B: Plungers with one cavity;

Type C: Plungers with two cavities.

3.2 Discs

Discs shall be classified as follows:

Type A: Trimmed discs;

Type B: Moulded discs.

4 Dimensions and designation

4.1 Plungers

4.1.1 Dimensions

The dimensions of plungers shall be as shown in Figure 1 and as given in Table 1. General dimensional tolerances shall be in accordance with ISO 3302.

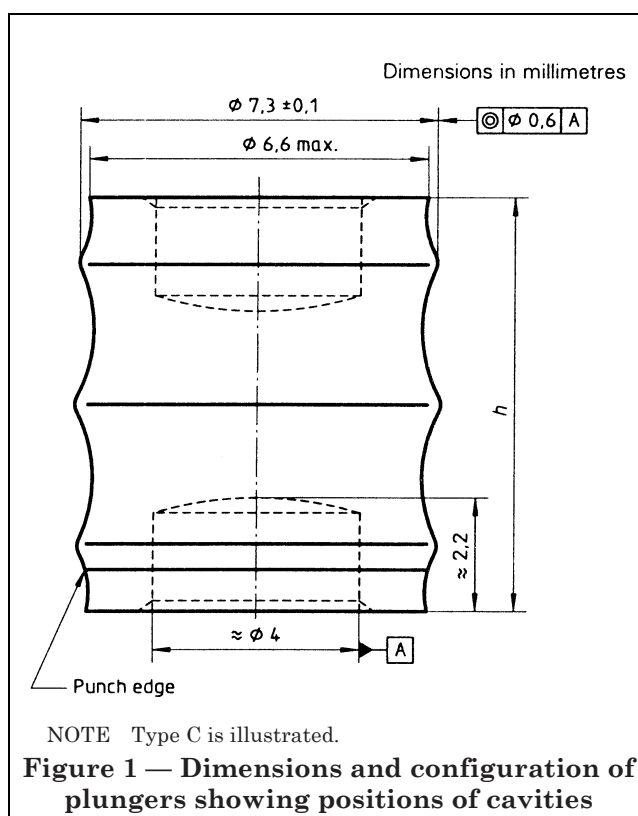


Table 1 — Dimensions of plungers

Dimensions in millimetres	
Type ^a	h $\pm 0,25$
A	6
B and C	8
^a See 3.1.	

¹⁾ To be published.